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| 09/997,694 | 11/30/2001 | Gerald Cowley | 301928.3000-100 | 4739 |
| 7590 11/17/2004 | | | | |
| Mark E. Waddell, Esq. Chadbourne & Parke LLP 30 Rockefeller Plaza New York, NY 10112 | | | EXAMINER CHORBAJI, MONZER R | |
| | | | ART UNIT 1744 | PAPER NUMBER |

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,694

Applicant(s)

COWLEY ET AL. *TH*

Examiner

MONZER R CHORBAJI

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 08/20/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

This non- final office action in response to the amendment received on 08/20/2004

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-11, 14-37, 39-49 and 52-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hedman et al (U.S.P.N. 6,327,812) in view of Rosenblatt et al (U.S.P.N. 4,681,739).

With regard to claims 1 and 39, the Hedman reference discloses a method for fumigating buildings (col.1, lines 5-7) by using ozone emitters (col.3, lines 46-49 and figure 1, 20) which was previously habitable and also teaches of removing ozone from buildings (figure 1, 22, 24, and 26) after completing treatment of the building (restoring habitability). With respect to "maintaining a residual amount" is a routine experimentation when dealing with something as large as a building in order to achieve the required decontamination of the contents within. In addition, the Hedman reference generates, introduces, distributes, and removes ozone from the enclosed space (figure 1, 22). However, the Hedman reference fails to disclose the presence of Bacillus spores, climatizing the enclosed volume and generating chlorine dioxide. The Rosenblatt reference discloses a method for fumigating an enclosed volume (col.4, lines 26-27) that contains contents including Bacillus spores (example 1) requiring fumigation (col.3, lines 22-23) including the following: climatizing the enclosed volume (col.4, lines 13-16), generating chlorine dioxide gas from a source which represent a generator (col.6, lines 1-3), introducing the chlorine dioxide gas into the enclosed volume to be fumigated such that an emitter is required to let the gas in the enclosed volume (col.6, lines 12-14), distributing the chlorine dioxide gas in the enclosed volume (col.4, lines 23-25), maintaining a residual amount of chlorine dioxide gas into the enclosed volume at a level (col.4, lines 20-23) and duration (col.4, lines 23-25) to penetrate the contents, and

removing the chlorine dioxide gas from the enclosed volume (col.6, lines 21-24). Thus, it would have been obvious to one having ordinary skill in the art to substitute one known sterilant (ozone) for another (chlorine dioxide) since chlorine dioxide sterilizes at short exposure times and at near ambient temperature and near ambient pressures (Rosenblatt et al, col.2, lines 67-68 and col.3, lines 1-2).

With respect to claims 2, 18, 40 and 53, the Rosenblatt reference al removes chlorine dioxide gas from the enclosed volume (col.6, lines 21-23) and then flushes the emitter and the enclosed volume with filtered inert gas (col.6, lines 21-24). Since the ('739) reference teaches that in one embodiment one stream is used to introduce and exhaust the sterilant (col.4, lines 47-50), then when purging occurs, the filtered inert gas will also include the chlorine dioxide generator. In addition, scrubbing of chlorine dioxide gas is disclosed in the Rosenblatt reference (col.6, lines 24-27). Further, the Rosenblatt reference produces chlorine dioxide gas (stripper) from a liquid solution (col.6, lines 1-11) and introduces chlorine dioxide gas into the enclosed volume using in one embodiment only one stream (col.4, lines 47-50).

With respect to claims 3-4 and 41-42, the Rosenblatt reference generates chlorine dioxide gas from an aqueous solution of chlorine dioxide gas in a liquid (col.6, lines 1-7).

With respect to claims 5 and 43, since the Rosenblatt reference teaches that in one embodiment only one stream is used (col.4, lines 47-50). Then the stream (emitter) introduces chlorine dioxide into the enclosed volume and scrubs chlorine dioxide after the end of a sterilization cycle. Thus, the emitter is a stripper (col.6, lines 21-27).

With respect to claims 6 and 44, the Hedman reference uses ozone emitters (col.3, lines 46-49 and figure 1, 20) in building, which was previously habitable and also teaches of removing ozone from buildings (figure 1, 22, 24, and 26) after completing treatment of the building (restoring habitability). However, fails to teach the use of a single means for introducing and for scrubbing chlorine dioxide gas. The Rosenblatt reference teaches the use of a single means for introducing and for scrubbing chlorine dioxide gas (col.4, lines 47-50 and col.6, lines 21-27). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Hedman reference by substituting a single means for introducing and scrubbing chlorine dioxide gas for multiple means as taught by the Rosenblatt reference since such a modification is a design choice well within the scope of the artisan.

With respect to claims 7-10, 14, 24, 45-48, 52 and 57, the Rosenblatt reference teaches the following: adjusting both the relative humidity and the temperature (col.3, lines 59-61 and col.4, lines 13-15), intrinsically avoids condensation by monitoring and controlling the dew point within the enclosed volume (col.4, lines 56-61), and reducing the level of illumination (col.5, lines 19-21).

With respect to claims 11 and 49, the Hedman reference teaches fumigating a building or an enclosed portion thereof (col.2, lines 50-52).

With respect to claims 15-17, 19-20, 25-30, 34-35, 58-63 and 66-67, the Rosenblatt reference method intrinsically involves such steps. See col.4, lines 20-26.

With respect to claims 21-23, 31-33, 54-56 and 64-65, the Rosenblatt reference teaches the following: The enclosed volume undergoes a vacuum (col.4, lines 34-35),

the chlorine dioxide solution inherently has an equilibrium partial pressure (col.6, lines 1-7), the sterilant gas penetrates the contents in the enclosed volume (abstract, lines 1-10), and the enclosed volume requiring fumigation is contaminated with any type of spore (abstract, lines 11-13) including Bacillus Anthracis. Furthermore, the Rosenblatt reference discloses various gram-positive spores (col.6, lines 48-51).

With respect to claims 36-37 and 68-69, the Rosenblatt reference teaches that in one embodiment only one stream is used (col.4, lines 47-50) to introduce the sterilant into the enclosed volume and to scrub the sterilant from the enclosed volume (col.6, lines 12-24). In addition, the Rosenblatt reference removes the sterilant by a detoxification treatment (col.6, lines 24-27).

5. Claims 12 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hedman et al (U.S.P.N. 6,327,812) in view of Rosenblatt et al (U.S.P.N. 4,681,739) and further in view of Smith et al (U.S.P.N. 4,780,333).

With respect to claims 12 and 50, both the Hedman reference and the Rosenblatt reference fail to provide a vehicle as an example for the enclosed volume. However, the Smith reference teaches treating a vehicle (col.6, lines 32-36). Thus, it would have been obvious to one having ordinary skill in the art to modify the Hedman reference and the Rosenblatt reference methods to include treating a vehicle since there is an established relationship between respiratory ailment symptom and automobile air conditioning (col.1, lines 52-54).

6. Claims 13 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hedman et al (U.S.P.N. 6,327,812) in view of Rosenblatt et al (U.S.P.N. 4,681,739) and further in view of Halaby, Jr. (U.S.P.N. 4,272,019).

With respect to claims 13 and 51, both the Hedman reference and the Rosenblatt reference fail to teach distributing the sterilant by using heating ventilation and an air conditioning system. However, the Halaby reference teaches distributing deodorants and insecticides using an air conditioning system (col.11, lines 5-14 and lines 24-29). Thus, it would have been obvious to one having ordinary skill in the art to modify the Hedman reference and the Rosenblatt reference methods to include using air conditioning systems in order to gain access to another area to be treated (col.11, lines 26-29).

7. Claims 38 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hedman et al (U.S.P.N. 6,327,812) in view of Rosenblatt et al (U.S.P.N. 4,681,739) and further in view of Spink (U.S.P.N. 5,565,180).

With respect to claims 38 and 70, both the Hedman reference and the Rosenblatt reference fail to teach removing the sterilant using an aqueous mixture of a bisulfite and caustic. However, the Spink reference teaches that the use of an aqueous mixture of a bisulfite and caustic (col.20, lines 11-16) is known for treating gases including chlorine dioxide (col.14, lines 40-44 and col.19, lines 28-32). Thus, it would have been obvious to one having ordinary skill in the art to substitute one known detoxification process as disclosed in the Rosenblatt reference for another (the Spink reference, col.20, lines 11-

16) since such an aqueous mixture removes chlorine dioxide gas from emissions (col.19, lines 30-32).

Response to Arguments

8. Applicant's arguments filed 08/20/2004 have been fully considered but they are not persuasive.

On page 12 of the Remarks section, applicant argues that, "Regarding claim 1, Hedman discloses a method for destroying and removing organisms and toxins from an enclosure, such as a building, using an environmentally acceptable gas that is heated at high temperatures." The examiner disagrees. The Hedman reference combines a gas such as air with ozone (col.4, lines 10-14). Ozone is not an environmentally acceptable gas since the Journal of Applied Bacteriology reference submitted IDS shows ozone decomposer (L) is used before ozone is exhausted into the environment.

On pages 12-13 of the Remarks section, applicant argues that, "The chlorine dioxide fact sheet does not list fumigation of habitable structures as a registered use for liquefied or gaseous chlorine dioxide." The examiner disagrees. The fact sheet, on page 2, under the subtitle "Registered Uses for Chlorine Dioxide", teaches that chlorine dioxide is known to sterilize clean rooms. Clean rooms are habitable structures.

On page 13 of the Remarks section, applicant argues that, "In fact, chlorine dioxide could not lawfully be used in fumigating a building until and emergency order was issued in the form of a crisis exemption under FIFRA in response to the anthrax contamination of the Hart Senate Office Building in the fall of 2001." First as mentioned above, the fact sheet, on page 2, under the subtitle "Registered Uses for Chlorine

Dioxide", teaches that chlorine dioxide is known to sterilize clean rooms. Clean rooms are habitable structures. Second, the FIFRA memo mentions that the sale of chlorine gas generating source is limited under normal condition and under proper safety guidelines using chlorine dioxide is not unlawful. Also, the fact that something is momentarily "unlawful" does not mean that it is unobvious. Regulatory law is not the same as patent law. One may not be able to sell a new drug (not approved by the FDA) but the drug may well be patentable.

On page 13 of the Remarks section, applicant argues that, "In the regulatory environment, Hedman's requirement to use an environmentally acceptable gas precludes the choice of chlorine dioxide." As mentioned above, the Hedman reference combines a gas such as air with ozone (col.4, lines 10-14). Ozone is not an environmentally acceptable gas since the Journal of Applied Bacteriology reference submitted IDS shows ozone decomposer (L) is used before ozone is exhausted into the environment. Thus, it would have been obvious to one having ordinary skill in the art to substitute one known sterilant (ozone) for another (chlorine dioxide) since chlorine dioxide sterilizes at short exposure times and at near ambient temperature and near ambient pressures (the Rosenblatt reference, col.2, lines 67-68 and col.3, lines 1-2).

On page 14 of the Remarks section, applicant argues that, "Proper characterization of one of ordinary skill and a recognition of the EPA regulations is part of the prior art precludes the combination of Hedman and Rosenblatt." As mentioned above, the fact sheet, on page 2, under the subtitle "Registered Uses for Chlorine Dioxide", teaches that chlorine dioxide is known to sterilize clean rooms. Clean rooms

are habitable structures. In addition, the FIFRA memo mentions that the sale of chlorine gas generating source is limited under normal condition and under proper safety guidelines using chlorine dioxide is not unlawful. As a result, one ordinary skill in the art reading about the prior application of gaseous chlorine dioxide to habitable structures and that the EPA permission to use chlorine dioxide gas only by following strict safety guidelines would have been motivated to substitute one known sterilant (ozone) for another (chlorine dioxide) since chlorine dioxide sterilizes at short exposure times and at near ambient temperature and near ambient pressures (the Rosenblatt reference, col.2, lines 67-68 and col.3, lines 1-2).

On page 14 of the Remarks section, applicant argues that, "Applicant finds no arguments with respect to claim 6 in view of Rosenblatt." Claim 6 has been re-addressed in view of the Rosenblatt reference.

On page 15 of the Remarks section, applicant argues that, "Applicant's claim 21 does not teach a vacuum." The examiner disagrees. Maintaining the volume at a slightly negative pressure compared to areas outside of the volume is equivalent to drawing a vacuum on the volume whether the value of the vacuum is slight or large.

On page 16 of the Remarks section, applicant argues that, "Now where does Smith teach disinfection of the entire passenger compartment of organisms existing anywhere other than the air conditioning ductwork." The Smith reference is combined for the single concept of treatment in a vehicle (col.6, lines 32-36) and not for whether the entire passenger compartment has been treated or for reducing the humidity level in the air conditioning duct when humidity levels approach 70%. In addition, since the Hedman

reference fumigates a previously habitable enclosed volume, the combination of the Hedman reference with the Smith reference would lead one skilled in the art to fumigate the enclosed volume of a vehicle since there is an established relationship between respiratory ailment symptom and automobile air conditioning (the Smith reference, col.1, lines 52-54).

On page 17 of the Remarks section, applicant argues that, "Halaby does not purport to be an HVAC system implicitly nor explicitly." The examiner disagrees. The Halaby reference teaches distributing deodorants and insecticides using an air-conditioning system (col.11, lines 5-14 and lines 24-29) ducts. Furthermore, the Halaby reference teaches that the apparatus can be used in hospitals (col.11, lines 35-36) such that hospitals intrinsically include HVAC systems for providing a controlled environment within.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.
10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1744

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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